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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,369	01/28/2004	Shawn K. Horner	SHP026.4.3	2886
26152	7590	06/23/2005	EXAMINER	
SPECIALIZED HEALTH PRODUCTS INTERNATIONAL INC. 585 WEST 500 SOUTH BOUNTIFUL, UT 84010-8321			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/766,369	HORNER ET AL.
	Examiner	Art Unit
	Brian Szmal	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4-12-04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 11-18 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaillancourt et al (2003/0114797 A1) in view of Brimhall et al (6,004,294).

Vaillancourt et al disclose a safety needle and further disclose a first housing being configured to actuate a needle cannula disposed therewith; a second housing being releasably engageable with the first housing, the needle cannula being disposed for slidable movement with the second housing such that the second housing is extensible from a retracted position to an extended position to enclose a distal end of the needle cannula; the second housing including a binding member that defines binding surfaces that form an aperture configured for slidable receipt of the needle cannula between the retracted position and the extended position; the needle cannula includes a cutting edge; the second housing includes a handle, the handle defining a cavity configured for receipt of the first housing such that the first housing is releasably engageable with the second housing; the first housing includes a handle; the first housing is releasably engageable with the second housing; the first housing is releasably engageable with the second housing by means of an operable release; the first housing includes a locking configuration that mates with a groove of the second housing to facilitate releasable

engagement of the first housing and the second housing; the first housing includes an actuating mechanism that actuates the needle cannula; and the first housing includes a locking configuration that mates with a groove of the second housing to facilitate releasable engagement of the first housing and the second housing. See Figure 31; and Paragraph 0116.

Vaillancourt et al however fail to disclose the binding member including at least one drag inducing member such that the at least one drag inducing member engages the needle cannula during slidable receipt of the needle cannula to create a drag force with the needle cannula, the drag force and second housing facilitate rotation of the binding member relative to a longitudinal axis of the needle cannula such that the binding surfaces engage the needle cannula to prevent slidable movement of the needle cannula in the extended position of the second housing; the binding member further includes a needle communicating surface extending therefrom such that the needle communicating surface is engageable with the needle cannula to prevent rotation of the binding member; the binding member includes a substantially planar aperture plate that includes the binding surfaces that form the aperture; the at least one drag inducing member includes a pair of arms extending from the aperture plate; the second housing includes an inner housing that is disposed with the binding member; and the inner housing defines at least one blocking member extending from an interior surface thereof, the at least one blocking member being engageable with the binding member for urging the binding member to a binding orientation.

Brimhall et al disclose a needle assembly with a needle shield and further disclose the binding member including at least one drag inducing member such that the at least one drag inducing member engages the needle cannula during slidable receipt of the needle cannula to create a drag force with the needle cannula, the drag force and second housing facilitate rotation of the binding member relative to a longitudinal axis of the needle cannula such that the binding surfaces engage the needle cannula to prevent slidable movement of the needle cannula in the extended position of the second housing; the binding member further includes a needle communicating surface extending therefrom such that the needle communicating surface is engageable with the needle cannula to prevent rotation of the binding member; the binding member includes a substantially planar aperture plate that includes the binding surfaces that form the aperture; the at least one drag inducing member includes a pair of arms extending from the aperture plate; the second housing includes an inner housing that is disposed with the binding member; and the inner housing defines at least one blocking member extending from an interior surface thereof, the at least one blocking member being engageable with the binding member for urging the binding member to a binding orientation. See Figures 1, 3 and 5-9.

Since both Vaillancourt et al and Brimhall et al disclose means for shielding the distal end of a needle, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Vaillancourt et al to include the use of drag inducing members on the binding member, as per the teachings of Brimhall et al, since it would provide an alternate means of frictionally engaging the needle cannula. It

also would have been obvious to one of ordinary skill in the art to activate the operable release to selectively lock movement between the needle cannula and the inner needle, since it is well known in the art to lock the movement between the cannula and stylet in order to provide a means of efficiently cutting the acquired tissue sample with the outer cannula.

3. Claims 7-10, 19-22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaillancourt et al (2003/0114797 A1) and Brimhall et al (6,004,294) as applied to claims 1 and 23 above, and further in view of Bauer (5,313,958).
Vaillancourt et al and Brimhall et al, as discussed above, disclose a means of shielding the distal end of a needle, but fail to disclose the needle cannula includes an inner needle disposed for slidable movement with the needle cannula; the inner needle includes a lateral recess disposed adjacent a distal end thereof; the inner needle includes a cutting edge; the actuating mechanism includes a slide mounted with the needle cannula, the slide facilitating axial movement of the needle cannula; the actuating mechanism includes a biasing member that engages the slide to bias the needle cannula in a distal direction; the actuating mechanism includes a trigger that is connected to the biasing member for actuation thereof; a spring means for maintaining the actuating assembly in a proximal position; and the actuating mechanism includes a spring biased slide mounted with the needle cannula, the slide facilitating axial movement of the needle cannula.

Bauer discloses a biopsy needle and further discloses a means of shielding the distal end of a needle, but fail to disclose the needle cannula includes an inner needle

disposed for slidable movement with the needle cannula; the inner needle includes a lateral recess disposed adjacent a distal end thereof; the inner needle includes a cutting edge; the actuating mechanism includes a slide mounted with the needle cannula, the slide facilitating axial movement of the needle cannula; the actuating mechanism includes a biasing member that engages the slide to bias the needle cannula in a distal direction; the actuating mechanism includes a trigger that is connected to the biasing member for actuation thereof; a spring means for maintaining the actuating assembly in a proximal position; and the actuating mechanism includes a spring biased slide mounted with the needle cannula, the slide facilitating axial movement of the needle cannula. See Column 3, lines 10-68; Column 4, lines 1-5; and Figures 1-6.

Since Vaillancourt et al, Brimhall et al and Bauer disclose means for obtaining biopsy samples from the body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Vaillancourt et al and Brimhall et al to include the specifics of the biopsy device, as per the teachings of Bauer, since it would provide a means of obtaining a tissue sample. It also would have been obvious to one of ordinary skill in the art to selectively lock movement between the needle cannula and the inner needle, since it is well known in the art to lock the movement between the cannula and stylet in order to provide a means of efficiently cutting the acquired tissue sample with the outer cannula.

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vaillancourt et al (2003/0114797 A1) and Brimhall et al (6,004,294) in view of Bauer (5,313,958).

Vaillancourt et al, as discussed above, disclose a safety needle with a collapsible sheath and further disclose a base including a handle, the handle defining a cavity configured for receipt of the first housing such that the first housing is releasably engageable with the second housing, the needle cannula being disposed for slidable movement with the second housing such that the second housing is extensible from a retracted position to an extended position to enclose a distal end of the needle cannula, the second housing including an inner housing that supports a binding member, the binding member having an aperture plate, the aperture plate defining binding surfaces that form an aperture configured for slidable receipt of the needle cannula between the retracted position and the extended position. See Figure 31; and Paragraph 0116.

Brimhall et al, as discussed above, disclose a needle assembly with a needle shield and further disclose the binding member including a pair of friction members that engage the needle cannula during slidable receipt of the needle cannula to create a drag force with the needle cannula, the drag force facilitates rotation of the binding member relative to a longitudinal axis of the needle cannula such that the binding surfaces engage the needle cannula to prevent slidable movement of the needle cannula in the extended position of the second housing, wherein the binding member further includes a needle communicating surface extending therefrom such that the needle communicating surface is engageable with the needle cannula to prevent rotation of the binding member. See Figures 1, 3 and 5-9.

Both Vaillancourt et al and Brimhall et al, however, fail to disclose a core including a spring biased actuating mechanism that actuates a needle cannula disposed therewith,

the actuating mechanism having a slide that is mounted with the needle cannula to facilitate axial movement thereof, the needle cannula including an inner needle disposed for slidable movement with the needle cannula, the inner needle including a lateral recess disposed adjacent a distal end thereof.

Bauer, as discussed above, disclose a biopsy instrument and further disclose a core including a spring biased actuating mechanism that actuates a needle cannula disposed therewith, the actuating mechanism having a slide that is mounted with the needle cannula to facilitate axial movement thereof, the needle cannula including an inner needle disposed for slidable movement with the needle cannula, the inner needle including a lateral recess disposed adjacent a distal end thereof. See Column 3, lines 10-68; Column 4, lines 1-5; and Figures 1-6.

Since Vaillancourt et al, Brimhall et al and Bauer disclose means for obtaining biopsy samples from the body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Vaillancourt et al and Brimhall et al to include the specifics of the biopsy device, as per the teachings of Bauer, since it would provide a means of obtaining a tissue sample.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BS


MAX F. HINDENBURG
SUPPLYING PATENT EXAMINER
TECHNOLOGY CENTER 3700